

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

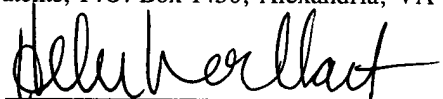
Applicant: McCluskie et al.  
Serial No: 09/316,199  
Confirmation No: 7506  
Filed: May 21, 1999  
For: METHODS AND PRODUCTS FOR INDUCING  
MUCOSAL ACTIVITY

Examiner: Dave Nguyen  
Art Unit: 1632

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**CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8(a)**

The undersigned hereby certifies that this document is being placed in the United States mail with first-class postage attached, addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the 20 day of November, 2003.



Helen C. Lockhart

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Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**STATEMENT FILED PURSUANT TO THE DUTY OF  
DISCLOSURE UNDER 37 CFR §§1.56, 1.97 AND 1.98**

Sir:

Pursuant to the duty of disclosure under 37 C.F.R. §§1.56, 1.97 and 1.98, the Applicant requests consideration of this Information Disclosure Statement.

**Compliance with 37 C.F.R. §1.97**

This Information Disclosure Statement has been filed more than three months after the filing date of this application and after the mailing date of the first Office Action, but before the mailing date of either a final action under 37 C.F.R. §1.113 or a Notice of Allowance under 37 C.F.R. §1.311, or an action that otherwise closes prosecution in this application.

1. The fee of \$180.00 as set forth in 37 C.F.R. §1.17(p) is enclosed.

Information Cited

The Applicant hereby makes of record in the above-identified application the information listed on the attached form PTO-1449 (modified). The order of presentation of the references should not be construed as an indication of the importance of the references.

The applicant would like to bring to the Examiner's attention the following co-pending applications that may contain subject matter related to this application:

Docket Number	Serial Number	Filing Date	Inventor(s)
C1037.70013US00	09/776,479	2/2/01	Bratzler et al.
C1037.70016US00	09/009,634	1/20/98	Hutcherson et al.
C1037.70018US00	09/801,839	3/8/01	Bratzler et al.
C1037.70019US00	09/920,313	8/1/01	Bratzler et al.
C1037.70021US00	09/949,194	9/7/01	Peterson et al.
C1037.70025US00	10/017,995	12/14/01	Bratzler
C1037.70041US00	10/613,749	7/3/03	Krieg
C1037.70042US00	10/613,524	7/3/03	Krieg
C1037.70043US00	10/613,739	7/3/03	Krieg
C1037.70044US00	10/613,736	7/3/03	Krieg
C1037.70045US00	10/613,228	7/3/03	Krieg
C1037.70046US00	10/455,247	6/5/03	Krieg
C1037.70048US00	10/644,052	8/19/03	Krieg et al.
C1037.70049US00	10/643,141	8/18/03	Hutcherson et al.
C1037.70051US00	10/666,733	9/19/03	Bratzler et al.
C1037.70052US00	10/666,050	9/22/03	Bratzler et al.
C1039.70022US00	09/337,893	6/21/99	Krieg
C1039.70028US00	09/361,575	7/27/99	Krieg
C1039.70029US00	09/415,142	10/9/99	Krieg et al.
C1039.70035US00	09/669,187	09/25/00	Krieg et al.
C1039.70036US00	09/559,140	4/27/00	Noll et al.
C1039.70041US00	09/655,319	9/5/00	Krieg et al.
C1039.70042US00	09/630,319	7/31/00	Krieg et al.
C1039.70043US00	09/629,477	7/31/00	Krieg et al.
C1039.70044US00	09/672,126	9/27/00	Hartmann et al.
C1039.70048US00	09/818,918	3/27/01	Krieg et al.
C1039.70049US00	09/824,468	04/02/01	Krieg et al.
C1039.70052US00	09/888,326	6/22/01	Weiner et al.
C1039.70053US00	09/931,583	8/16/01	Krieg et al.
C1039.70057US00	09/965,101	9/26/01	Davis et al.
C1039.70058US00	10/023,909	12/18/01	Davis et al.

Docket Number	Serial Number	Filing Date	Inventor(s)
C1039.70060US00	10/112,653	3/29/02	Krieg et al.
C1039.70061US00	10/161,229	6/3/02	Krieg et al.
C1039.70062US00	10/187,489	7/2/02	Krieg et al.
C1039.70063US00	10/224,523	8/19/02	Krieg et al.
C1039.70065US00	10/272,502	10/15/02	Krieg et al.
C1039.70067US00	10/300,247	11/20/02	Davis et al.
C1039.70068US00	10/306,522	11/27/02	Krieg et al.
C1039.70069US00	10/314,578	12/9/02	Krieg et al.
C1039.70070US00	10/382,822	3/6/03	Krieg et al.
C1039.70071US00	10/435,656	5/9/03	Krieg et al.
C1039.70072US00	10/434,696	5/9/03	Davis et al.
C1039.70075US00	10/613,916	7/3/03	Krieg et al.
C1039.70077US00	10/619,279	7/14/03	Krieg
C1039.70078US00	10/627,331	7/25/03	Krieg et al.
C1039.70079US00	10/627,413	7/25/03	Krieg et al.
C1039.70082US00	TBD	7/30/03	Krieg et al.
C1039.70083US00	10/690,495	10/21/03	Krieg
C1039.70084US00	10/649,584	8/25/03	Krieg et al.
C1040.70010US00	09/768,012	1/22/01	Davis et al.
C1041.70002US00	09/241,653	2/2/99	Wagner et al.
C1041.70005US00	09/355,254	7/23/99	Wagner et al.
C1041.70014US00	09/895,007	6/28/01	Schetter et al.
C1041.70016US00	09/954,987	9/17/01	Bauer et al.
C1041.70019US00	10/140,013	5/6/02	Schetter et al.
C1041.70029US00	10/212,133	8/1/02	Lipford et al.
C1041.70031US00	10/265,072	10/5/02	Lipford
C1041.70035US00	10/373,381	2/24/03	Wagner et al.
C1041.70037US00	10/407,952	4/4/03	Lipford et al.

### Remarks

Documents cited anywhere in the Information Disclosure Statement are enclosed unless otherwise indicated. It is respectfully requested that:

1. The Examiner consider completely the cited information, along with any other information, in reaching a determination concerning the patentability of the present claims;
2. The enclosed form PTO-1449 be signed by the Examiner to evidence that the cited information has been fully considered by the Patent and Trademark Office during the examination of this application;

3. The citations for the information be printed on any patent which issues from this application.

By submitting this Information Disclosure Statement, the Applicant makes no representation that a search has been performed, of the extent of any search performed, or that more relevant information does not exist.

By submitting this Information Disclosure Statement, the Applicant makes no representation that the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. §1.56(b).

By submitting this Information Disclosure Statement, the Applicant makes no representation that the information cited in the Statement is, or is considered to be, in fact, prior art as defined by 35 U.S.C. §102.

Notwithstanding any statements by the Applicant, the Examiner is urged to form his own conclusion regarding the relevance of the cited information.

An early and favorable action is hereby requested.

Respectfully submitted,  
McCluskie et al., *Applicant*

By: \_\_\_\_\_



Helen C. Lockhart, Ph.D., Reg. No. 39,248  
Wolf, Greenfield & Sacks, P.C.  
600 Atlantic Avenue  
Boston, Massachusetts 02210-2211  
Telephone: (617) 720-3500

Docket No. C1040.70006US00

Date: November 26, 2003

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<b>FORM PTO-1449/A and B (Modified)</b>  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>				APPLICATION NO.: 09/316,199		ATTY. DOCKET NO.: C1040.70006US00	
				FILING DATE: May 21, 1999		CONFIRMATION NO.: 7506	
				APPLICANT: McCluskie et al.			
				GROUP ART UNIT: 1632		EXAMINER: Dave Nguyen	
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#### U.S. PATENT DOCUMENTS

Examiner's Initials	Cite No.	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication or of issue of Cited Document MM-DD-YYYY
		Number	Kind Code		
	A1	6,174,872		Carson et al.	01/16/2001
	A2	6,194,388		Krieg et al.	02/27/2001
	A3	6,207,646		Krieg et al.	03/27/2001
	A4	6,214,806		Krieg et al.	04/10/2001
	A5	6,218,371		Krieg et al.	04/17/2001
	A6	6,239,116		Krieg et al.	05/29/2001
	A7	6,339,068		Krieg et al.	01/15/2002
	A8	6,406,705		Davis et al.	06/18/2002
	A9	6,429,199		Krieg et al.	08/06/2002
	A10	6,514,948		Raz et al.	02/04/2003
	A11	6,562,798		Schwartz	05/13/2003
	A12	6,589,940		Raz et al.	07/08/2003
	A13	6,610,661		Carson et al.	08/26/2003
	A14	6,613,751		Raz et al.	09/02/2003

#### FOREIGN PATENT DOCUMENTS

Examiner's Initials	Cite No.	Foreign Patent Document			Name of Patentee or Applicant of Cited Document (not necessary)	Date of Publication of Cited Document MM-DD-YYYY	Translation (Y/N)
		Office/Country	Number	Kind Code			
	/	US	20020055477A1		Nest et al.	05/09/2002	
	/	US	20020142978A1		Raz et al.	10/03/2002	
	/	US	20020156003A1		Bratzler et al.	10/24/2002	
	/	US	20030026782A1		Krieg et al.	02/06/2003	
	/	US	20030049266A1		Fearson et al.	03/13/2003	
		US	20030050263A1		Krieg et al.	03/15/2003	
	/	US	20030078223A1		Raz et al.	04/24/2003	
	/	US	20030092663A1		Raz	05/15/2003	
	/	US	20030109469A1		Carson et al.	06/12/2003	
	/	US	20030119773A1		Raz et al.	06/26/2003	
	/	US	20030147870A1		Raz et al.	08/07/2003	
	/	US	20030186921A1		Carson et al.	10/02/2003	
		WO	98/16247		The Regents of The University of California	04/23/1998	
		WO	99/11275		The Regents of The University of California	03/11/1999	
		WO	99/62923		Dynavax	12/09/1999	
		WO	00/20039		The Regents of The University of California	04/13/2000	
		WO	00/21556 A1		Dynavax	04/20/2000	
		WO	01/02007 A1		The Regents of The University of California	01/11/2001	
	/	WO	01/12223 A2		Dynavax	02/22/2001	

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				GROUP ART UNIT: 1632		EXAMINER: Dave Nguyen	
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**OTHER ART — NON PATENT LITERATURE DOCUMENTS**

Examiner's Initials	Cite No	Include name of the author (in CAPITAL LETTERS) title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, relevant page(s), volume-issue number(s), publisher, city and/or country where published.	Translation (Y/N)
	<del>C1</del>	Choi AH et al., "The level of protection against rotavirus shedding in mice following immunization with a chimeric VP6 protein is dependant on the route and the coadministered adjuvant", <i>Vaccine</i> . 2002 Mar 15;20(13-14): 1733-40.	
	<del>C2</del>	Davis, HL, "Use of CpG DNA for enhancing specific immune responses", <i>Curr Top Microbiol Immunol</i> . 2000; 247: 171-83.	
	<del>C3</del>	Dumais, N. et al., "Mucosal immunization with inactivated human immunodeficiency virus plus CpG oligodeoxynucleoties induce genital immune responses and protection against intravaginal challenge", <i>J. Infect. Dis</i> . 2002 Oct 15; 186(8):1098-105. Epub 2002 Sept.	
	<del>C4</del>	Gallichan, W. Scott et al., "Intranasal Immunization with CpG Oligodeoxynucleotides as an Adjuvant Dramatically Increases IgA and Protection Against Herpes Simplex Virus-2 in the Genital Tract", <i>The Journal of Immunology</i> , 2001, 166: 3451-3457.	
	<del>C5</del>	Hartmann, G et al., "Delineation of a CpG Phosphorothiaote Oligodeoxynucleotide for Activating Primate Immune Responses In Vitro and In Vivo", <i>The Journal of Immunology</i> , 2000, 164: 1617-1624.	
	<del>C6</del>	Kovarik, J et al., "CpG Oligodeoxynucleotides Can Circumvent the Th2 Polarization of Neonatal Responses to Vaccines But May Fail to Fully Redirect Th2 Responses Established by Neonatal Priming", <i>The Journal of Immunology</i> , 1999, 162: 1611-1617.	
	<del>C7</del>	Kovarik, J et al., "Adjuvant effect of CpG oligodeoxynucleotides on responses against T-independent type 2 antigens", <i>Immunology</i> . 2001 Jan; 102(1): 67-76..	
	<del>C8</del>	Krieg, AM et al., "Bacterial DNA or oligonucleotides containing CpG motifs protect mice from lethal <i>L. monocytogenes</i> challenge", Abstract from 1996 meeting on <i>Molecular Approaches to the Control of Infectious Diseases</i> , Cold Spring Harbor Laboratory, September 9-13, 1996. p.116.	
	<del>C9</del>	Krieg, AM, "CpG oligoneucleotides as immune adjuvants", <i>Ernst Schering Res. Found Workshop</i> , 2000; (30): 105-18.	
	<del>C10</del>	Krieg, AM, "Immune Effects and mechanisms of action of CpG motifs", <i>Vaccine</i> . 2001 Nov. 8; 19(6): 618-22.	
	<del>C11</del>	Krieg, AM et al., "Enhancing vaccines with immune stimulatory CpG DNA", <i>Curr Opin Mol Ther</i> . 2001 Feb; 3(1):15-24	
	C12	Liu, Hsin-Ming et al., "Immunostimulatory CpG Oligodeoxynucleotides Enhance the Immune Responses to Vaccine Strategies Involving Granulocyte-Macrophage Colony-Stimulating Factor", <i>Blood</i> , Vol 92, No. 10 (November 15), 1998: pp 3730-3736	
	<del>C13</del>	Malanchere-Bres, E et al., "CpG Oligodeoxynucleotides with Hepatitis B Surface Antigen (HBsAg) for Vaccination in HBsAg-Transgenic Mice", <i>Journal of Virology</i> , July 2001, p. 6482-6491	
	<del>C14</del>	Brazolot Millan, Cynthia L. et al., "CpG DNA can induce strong Th1 humoral and cell-mediated immune responses against hepatitis B surface antigen in young mice", <i>Proc. Natl. Acad. Sci. USA</i> , Vol. 95, pp. 15553-15558, December 1998 Immunology	
	<del>C15</del>	McCluskie, MJ et al., "Muscol immunization with DNA vaccines", <i>Microbes Infect</i> . 1999 Jul; 1(9): 685-98.	
	<del>C16</del>	McCluskie, MJ et al., "CpG DNA as mucosal adjuvant", <i>Vaccine</i> . 1999 Sep; 18(3-4): 231-7.	
	C17	McCluskie, MJ et al., "The role of CpG in DNA vaccines", <i>Springer Semin Immunopathol</i> . 2000; 22(1-2): 125-32.	
	<del>C18</del>	McCluskie, MJ et al., "CpG DNA is an effective oral adjuvant to protein antigens in mice", <i>Vaccine</i> . 2000 Nov 22; 19(7-8): 950-7.	
	<del>C19</del>	McCluskie, MJ et al., "Intranasal immunization of mice with CpG DNA induces strong systematic and mucosal responses that are influenced by other mucosal adjuvants and antigen distribution", <i>Mol Med</i> . 2000 Oct; 6(10): 867-77.	

<b>FORM PTO-1449/A and B (Modified)</b>  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>				APPLICATION NO.: 09/316,199		DOCKET NO.: C1040.70006US00	
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Sheet	3	of	3				

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	C20	McCluskie, MJ et al., "Oral, intrarectal and intranasal immunizations using CpG and non-CpG oligodeoxynucleotides as adjuvants", <i>Vaccine</i> 19 (2001) 413-422		
	C21	McCluskie, MJ et al., "The potential of CpG oligodeoxynucleotides as muscol adjuvants", <i>Crit Rev Immunol.</i> 2001; 21(1-3): 103-20		
	C22	McCluskie, MJ et al., "The use of CpG DNA as mucosal vaccine adjuvant", <i>Curr Opin Investig Drugs.</i> 2001 Jan; 2(1): 35-9.		
	C23	McCluskie, MJ et al., "The potential of oligodeoxynucleotides as mucosal and parenteral adjuvants", <i>Vaccine.</i> 2001 Mar 21; 19(17-19): 2657-60.		
	C24	McCluskie, MJ et al., "Mucosal immunization of mice using CpG DNA and/or mutants of the heat-labile enterotoxin of Escherichia coli as adjuvants", <i>Vaccine.</i> 2001 Jun 14; 19(27): 3759-68.		
	C25	McCluskie, MJ et al., "Parenteral and mucosall prime-boost immunization strategies in mice with hepatitis B surface antigen and CpG DNA", <i>FEMS Immunol Med Microbiol.</i> 2002 Feb 18; 32(3): 179-85.		
	C26	Pal, S. et al., "Immunization with the Chlamydia trachomatis mouse pneumonitis major outer membrane protein by use of CpG oligodeoxynucleotides as an adjuvant induces a protective immune response against an intranasal chlaymdial challenge", <i>Infect Immun.</i> 2002 Sep; 70(9): 4812-7.		
	C27	Payette PJ et al., "History of vaccines and positioning of current trends", <i>Curr Drug Targets Infect Disord.</i> 2001 Nov; 1(3): 241-7.		
	C28	Sajic D et al., "Parameters of CpG oligodeoxynucleotide-induced protection against intravaginal HSV-2 challenge", <i>J Med Virol.</i> 2003 Dec; 71(4):561-568.		
	C29	Weeratna, RD et al., "CpG ODN allows lower doses of antigen against hepatitis B surface antigen in BALB/c mice", <i>Immunol Cell Biol.</i> 2003 Feb; 81(1): 59-62.		
	C30	Weeratna, RD et al., "CpG ODN can redirect the Th bias of established Th2 immune responses in adult and young mice", <i>FEMS Immunol Med Microbiol.</i> 2001 Dec; 32(1): 65-71.		
	C31	Weeratna, RD., "Priming of immune responses to hepatitis B surface antigen in young mice immunized in the presence of maternally derived antibodies", <i>FEMS Immunol Med Microbiol.</i> 2001 Apr; 30(3): 241-7.		
	C32	Weeratna, RD, "CpG DNA induces stronger immune responses with less toxicity than other adjuvants", <i>Vaccine.</i> 2000 Mar 6; 18(17): 1755-62.		

EXAMINER	DATE CONSIDERED
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#EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.